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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting consumer representatives and nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2001.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups, as well as nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations should be received by *[insert date 30 days after date of publication in the Federal Register]*, for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for consumer representatives should be submitted in writing to Mary C. Wallace (address below). All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for industry representatives should be submitted in writing to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding consumer representatives: Mary C. Wallace, Office of Consumer Affairs (HFE-

3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 301-827-4406, e-mail: MWALLACE@OC.FDA.GOV.

Regarding industry representatives: Kathleen L. Walker, Office of Systems and Management (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting members representing consumer and industry interests for the vacancies listed below:

Medical Devices Panels	Approximate Date Representative is Needed	
	Consumer	Industry
Circulatory System Devices Panel	NV ¹	July 1, 2001
Dental Products Panel	November 1, 2000	NV ¹
Ear, Nose & Throat Devices Panel	NV ¹	November 1, 2000
Immunology Devices Panel	NV ¹	March 1, 2001
Neurological Devices Panel	December 1, 2000	December 1, 2000
Obstetrics & Gynecology Devices Panel	February 1, 2001	February 2, 2001
Orthopaedic & Rehabilitation Devices Panel	NV ¹	September 1, 2000

¹ NV = No vacancy

I. Function

The functions of the medical device panels are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Consumer and Industry Representation

Section 520(f)(3) of the act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

III. Nomination Procedures

A. Consumer Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Nominations shall include a complete curriculum vitae of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

B. Industry Representatives

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore,

recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vita of each nominee. The term of office is up to 4 years, depending on the appointment date.

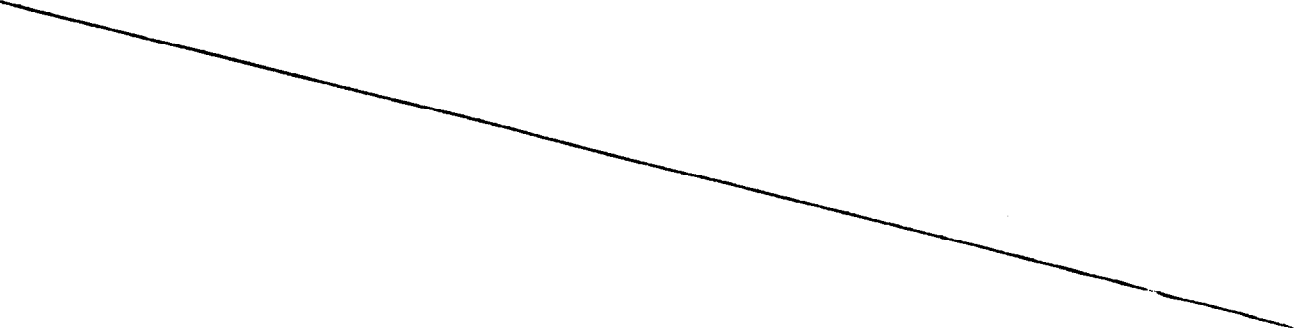
IV. Selection Procedures

A. Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

B. Industry Representatives

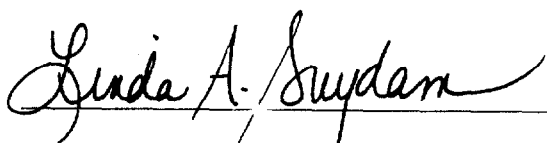
Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: 08-04-00

August 4, 2000



Linda A. Suydam,
Senior Associate Commissioner.

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